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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,684	02/18/2004	Mark W. Kroll	A04P1016	5251

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,684	KROLL, MARK W.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,13-20 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,13-20 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was confirmed **without** traverse in the reply filed on 08 December 2006.

2. Claims 10, 12 and 21-22 are cancelled; claims 1-9, 11, 13-20 and 23-25 are pending.

Specification

3. In view of the amendments received 08 December 2006, the examiner withdraws the objection to the specification.

Claim Objections

By way of clarification of the previous objection to claim 18, the examiner would like to note that it is unclear whether it is the circumstances or the recording of the medical data that actually occurred (lines 2-3 of the claim). It is to be further noted that line 5 of the claim should also be grammatically clarified, specifically the phrase "the risk of unnecessarily recording of diagnostic data." The objection to this claim is maintained.

Response to Arguments

4. Applicant's arguments filed 08 December 2006 have been fully considered but they are not persuasive. The applicant argues (page 11-12, "Remarks") that Wilson's (Wilson et al U.S. 5,908,392) implantable system does not contain all of the claimed elements, including the amended subject matter. Specifically, the applicant argues, "Wilson discloses a system that continuously records data into temporary buffers without reference to any type of criteria. See column 8, lines 49-54. Upon meeting a particular criteria, data from the temporary buffers is transferred to a snap-shot buffer for long-term storage. See column 10, lines 16-25 and lines 41-44. Thus the Wilson system continuously records data." The examiner respectfully disagrees with this position. While it is true that Wilson's system continuously stores data related to cardiac events and waveforms, this storage is only temporary and can therefore not be considered to be recorded at all. Once a set of programmable trigger criteria is met, indicating a likely onset of an arrhythmia, the control system creates a data snapshot based on the collected data before and after the trigger criterion or criteria has been met. This snapshot, since it is transferred to a long-term memory, can be seen as recorded. See column 3, lines 20-40. The difference between the continuous storage of data and the recording of significant data snapshots is that the continuously gathered data is temporarily available and not permanently stored. The rejection of claims 1-3, 19-20 and 23-25 under Wilson is therefore maintained.

5. Applicant's arguments, see "Remarks," pages 9-10, filed 08 December 2006, with respect to Baker et al (2002/0147409) have been fully considered and are

persuasive. The rejection of claims 1-3, 12, 19-20 and 23-25 under Baker has been withdrawn.

6. Applicant's arguments, see "Remarks," pages 10-11, filed 08 December 2006, with respect to McClure et al (U.S. 6,275,734) have been fully considered and are persuasive. The rejection of claims 1, 2, 4 and 12 under McClure has been withdrawn.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 8-9, 11, 13, 19-20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (U.S. 5,908,392). For a full discussion of the claimed elements, please see above and the previous Non-Final Office Action.

9. Regarding claim 19, Wilson discloses the use of both IEGM (col. 5, lines 48-54) and event records (col. 3, lines 20-40) for diagnostic data.

10. Regarding claim 20, the examiner considers the data snapshot used by Wilson to provide data to long-term memory not only of likely cardiac events, but also of the cardiac events themselves, for example a cardiac arrhythmia that actually occurred.

11. Regarding claims 23 and 25, Wilson discloses (col. 5, lines 48-50; col. 6, lines 20-30) a dual chamber pacemaker including a control system that receives cardiac data such as IEGM, a memory operative to record diagnostic medical data associated with the cardiac rhythm and a risk-based diagnostic data controller operative to perform the claimed functions.

12. Regarding claim 24, Wilson discloses, (col. 16, lines 58-61) "a system and method are provided for recording and storing, in long-term memory and in form of data snapshots, medical data acquired prior to and subsequent to occurrence of cardiac episodes and implantable device functions defined as important by the medical practitioner." The examiner considers this to be an adaptive-based diagnostic controller operative to adaptively modify parameters employed to by the risk-based diagnostic data controller in making its evaluation so as to improve the reliability of such evaluations.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392); claims 15-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392). For a full discussion of the claimed elements, please see above and the previous Non-Final Office Action.

15. Claims 4 and 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392). Wilson discloses (col. 5, lines 55-60) the use of a control system that receives the output signals from a ventricular sense amplifier (32) over line (42). The output signals are generated each time that a ventricular event is sensed within the heart. Since the

device senses data from the ventricle, and uses data from all of the heart to record data based on a likely onset of an arrhythmia, the examiner considers the system to naturally identify periods of time wherein there is an elevated risk for ventricular fibrillation. In the alternative, it would have been obvious to one of ordinary skill in the art at the time of the invention to identify periods of time wherein there is an elevated risk for ventricular fibrillation in order to diagnose and mark a specific instance of a particular kind of arrhythmia, which is ventricular fibrillation.

16. Regarding claim 6, since the storing of the cardiac information is intended as a snapshot of a detected arrhythmia, the examiner considers it to be inherent in the system that this recording is deactivated if arrhythmia is not occurring. In the alternative, the examiner considers it to be obvious to one of ordinary skill in the art at the time of the invention to deactivate Wilson's long-term storage of diagnostic data in order to save space in the system memory.

17. Regarding claim 7, Wilson discloses the claimed invention except for deactivating the recording of diagnostic data after at least nine months. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use this fixed period, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

18. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392) in view of Sweeney et al (U.S. 6,400,982). Wilson discloses the claimed invention except for monitoring heart rate variability and identifying periods of

time with reduced heart rate variability. Sweeney however discloses (col. 7, lines 52-68; col. 8, lines 1-3) a method for use with an implantable system for predicting cardiac arrhythmias, which includes the steps of sensing cardiac parameters and predicting an arrhythmia based on arrhythmic triggers or markers. Some of these triggers include abnormal heart rate variability. Though Sweeney does not mention recording the diagnostic data, the invention can be used (col. 7, lines 48-51) with apparatus that include programmers and recorders. Further Sweeney and Wilson both disclose diagnostic systems for use with cardiac rhythm management. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wilson's diagnostic data recorder with Sweeney's heart rate variability detection in order to provide a parameter for recording that uses heart rate as a predictor for arrhythmia.

19. Regarding claim 5, Sweeney discloses (col. 2, lines 59-67; col. 3, lines 1-2) "an arrhythmia is predicted by: 1) detecting a conditioning event statistically associated with the occurrence of an arrhythmia in a patient's heart; 2) computing a conditional arrhythmia probability for the conditioning event from past observations of instances in which the conditioning event occurs alone or together with an arrhythmia within a specified time period; 3) computing an estimated arrhythmia probability based upon the detected occurrence of the conditioning event; and 4) predicting the occurrence of an arrhythmia within a specified prediction time period if the estimated arrhythmia probability exceeds a specified threshold value." The examiner considers this to be identifying a time subsequent to the predicted ventricular fibrillation as a risk period.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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